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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,331	11/09/2001	James C. Paulson	019957-011211US	3312

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EXAMINER	
PROUTY, REBECCA E	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,331	PAULSON ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57,59-70,101 and 112* is/are pending in the application.

4a) Of the above claim(s) *66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57,59-65, 67-70,101 and 112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-56, 58, 71-100 and 102-111 been canceled. Claims 57, 59-70, 101 and newly presented claim 112 are still at issue and are present for examination.

Applicants' arguments filed on 5/18/04, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim 66 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the response filed 10/15/03.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 57, 59-65, 67-70, 101, and 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Bergh et al (US Patent 5,272,066), Maras et al

(US Patent 5,834,251), Weinstein et al. (JBC 257: 13845) and Williams et al. (Glycoconjugate J. 12: 255). The rejection is explained in the previous Office Action.

Applicants argue that the examiner has not pointed to any specific teaching of large scale production of modified glycoproteins in the cited art. It was expressly acknowledged in the previous Office Action that the cited references did not expressly teach this limitation of the claims. However, the instant rejection was not made under 102, but under 103. While as previously stated this limitation was not explicitly shown by the cited references is clearly made obvious thereby. As previously stated, Maras et al. explicitly state that as a result of the described methods, that large-scale stereo-controlled oligosaccharide synthesis will be possible (see column 28, lines 52-67). Furthermore, even without such an explicit statement in the cited art, the instant limitation would have been obvious to the ordinary skilled artisan as it is the clear intention of both Bergh et al. and Maras et al. to provide methods of glycosylating proteins which are intended for therapeutic use. It is obvious on its face that this use is only practical if the proteins can be produced on a commercial scale. As such the suggestion to scale up the disclosed *in*

vitro methods is clearly implicit in the teaching of both primary references of the intended use of the products of their methods.

Applicants further argue that the rejection as applied to new claim 112 is improper as the rejection provides no reasoning or evidence to show that one of skill would have a reasonable expectation that recombinantly produced enzymes could be successfully used in commercial scale methods that achieve high level of sialylation as claimed here. This is not persuasive because the rejection explicitly suggested using a recombinantly produced sialyltransferase because recombinant production provides a economical means of producing the large quantities of enzyme that would be necessary for the claimed commercial scale methods. Applicants argue that Williams shows that recombinant sialyltransferases generally had lower affinity (higher K_m) for substrate (CMP-NeuAc, oligosaccharide or glycoprotein), as compared to the native enzymes and that the specific activity of the recombinantly produced α2,3 sialyltransferase had a specific activity about 1/3 of that of the native enzyme (see page 760, bottom of left column). This is not persuasive because such characteristics would merely alter **the amount** of the enzyme needed to achieve catalysis that would need to be used. While

it might be true that larger quantities of recombinant enzyme would be required than would be necessary if native enzyme were used, this would not teach away from using recombinant enzyme as recombinant production expressly provides the quantities necessary while the isolation of large enough quantities of native enzyme would likely be economically impossible.

Applicants argue that the declaration of Dr. Zopf establishes that the instant invention solves a long-felt need in the art, has shown commercial success and shows the skepticism of the art that this was feasible. While applicants declaration is acknowledged, the declaration showing skepticism of a single artisan is not sufficient to show that the art as a whole clearly doubted the feasibility of the instant invention as the disclosures of Maras et al. and Bergh et al. which clearly suggest *in vitro* modification of glycoproteins with the intent of using them therapeutically is in direct opposition with the statements of Dr. Bailey. Both Bergh et al. and Maras et al. clearly do think that *in vitro* modification of glycoproteins is feasible. While the declaration provides some evidence of commercial success, there is no evidence, beyond merely a statement by Dr. Zopf, who is clearly not an impartial party, that the success demonstrated is a result of the merits

of the invention and not related to other factors. Furthermore, there is no evidence that the commercial success is linked to the specific limitations of the current claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 57, 59-65, 67-70, 101 and 112 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 57, 59-64, 66-69 and 82 of U.S. Patent No. 6,399,363. The rejection is explained in the previous Office Action.

Applicants did not address the instant rejection in the current response. As such the rejection is maintained for the reasons of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty

REBECCA B. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600